

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

CHERYL LANKSTON,

Plaintiff,

v.

CIVIL ACTION NO. 2:12-cv-00755

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Defendants' Motion for Summary Judgment)

Pending before the court is the defendants' Motion for Summary Judgment [ECF No. 93]. As set forth below, the defendants' Motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to the court by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 32,000 of which are in the Ethicon, Inc. and Johnson & Johnson, Inc. ("Ethicon") MDL, MDL 2327. In an effort to efficiently and effectively manage this massive MDL, the court decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled

on all summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, the court ordered the plaintiffs and defendant to submit a joint list of 200 of the oldest cases in the Ethicon MDL that name only Ethicon, Inc., Ethicon, LLC, and/or Johnson & Johnson. These cases became part of a “wave” of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order No. 193, *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002327, Aug. 19, 2015, *available at* <http://www.wvsc.uscourts.gov/MDL/ethicon/orders.html>. This selection process was completed three times, creating three waves of 200 cases, Wave 1, Wave 2, and Wave 3. The plaintiff’s case was selected as a Wave 1 case.

On March 9, 2011, Ms. Lankston was surgically implanted with the TVT-Secur (“TVT-S”), a product manufactured by Ethicon to treat POP and SUI. Am. Short Form Compl. ¶¶ 9–10 [ECF No. 17]. Ms. Lankston’s surgery occurred at Sweeny Community Hospital in Sweeny, Texas. *Id.* ¶ 11. Ms. Lankston claims that as a result of implantation of the TVT-S, she has experienced multiple complications. She brings the following claims against Ethicon: negligence, strict liability manufacturing defect, strict liability failure to warn, strict liability defective product, strict liability design defect, common law fraud, fraudulent concealment, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, breach of express and implied warranties, violation of consumer protection laws, gross negligence, unjust enrichment, punitive damages, and discovery rule and tolling. *Id.* ¶ 13.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731

F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Lankston did in this case, the court consults the

choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (“For cases that originate elsewhere and are directly filed into the MDL, the court will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.”). Ms. Lankston received the TVT-S implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide the court’s choice-of-law analysis.

These principles compel application of Texas law to the plaintiff’s claims.¹ In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws (Am. Law Inst. 1971). *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under section 145 of the Restatement (Second) of Conflict of Laws, the court must apply the law of the state with the most “significant relationship to the occurrence and the parties.” Here, the plaintiff resides in Texas, and the product was implanted in Texas. Thus, the court applies Texas’s substantive law to this case.

III. Analysis

Ethicon argues it is entitled to summary judgment because the plaintiff’s legal theories are without evidentiary or legal support. In her Response [ECF No. 106] the plaintiff withdraws several of the counts listed in her Amended Short Form

¹ Both parties assert that New Jersey law applies to the plaintiff’s punitive damages claims, but agree Texas law applies to all other claims. At this time, the court need not address the issue of which law applies to the punitive damages claims because Ethicon ultimately makes no argument regarding punitive damages.

Complaint: loss of consortium (XVI); ² negligent infliction of emotional distress (X); unjust enrichment (VX); manufacturing defect (II); breach of warranty (XI and XII); fraud (VI); fraudulent concealment (VII); constructive fraud (VIII); and Deceptive Trade and Practices Act (XIII). Accordingly, Ethicon's Motion with regard to these claims is **GRANTED**. Below, the court applies the summary judgment standard to each remaining claim.

A. Strict Liability

Texas has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts. *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967). Section 402A provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

² Ethicon asserts that the loss of consortium claim is barred under Texas law and the plaintiff concedes that summary judgment should be granted on this issue. However, the court notes that plaintiff did not actually assert a loss of consortium claim in her amended short form complaint.

Restatement (Second) of Torts § 402A (Am. Law Inst. 1965). “The concept of defect is central to a products liability action brought on a strict tort liability theory, whether the defect be in conscious design, or in the manufacture of the product, or in the marketing of the product.” *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

1. Design Defect

In Texas, a plaintiff bringing a design defect claim under strict liability must prove by a preponderance of the evidence that (1) the product was unreasonably dangerous due to a defect, (2) “there was a safer alternative design,” and (3) “the defect was a producing cause” of the damages. Tex. Civ. Prac. & Rem. Code Ann. § 82.005; *see also Timpfe Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009).

Ethicon’s Motion seeks summary judgment on the plaintiff’s design defect claims first on the basis that the plaintiff has failed to show the existence of a safer alternative design. To determine there was a safer alternative design, a plaintiff must prove that “an alternative design (i) would in reasonable probability have prevented or significantly reduced the risk of the claimant's injury or damage (ii) without substantially impairing the product's utility, and (iii) was economically and technologically feasible when the product was manufactured or sold.” *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999). Proving the existence of a safer alternative design is a prerequisite to liability under Texas law. *Id.*

The plaintiff has proffered extensive evidence of three alternative designs: (1)

non-laser cut mesh, (2) mesh made with material other than Prolene polypropylene, and (3) larger pore and lighter weight mesh. The plaintiff has produced evidence that these purported safer alternative designs would have reduced Ms. Lankston's injuries, would not have affected the product's utility, and would have been economically and technologically feasible. Accordingly, the court **FINDS** that there remains a genuine dispute of material fact regarding the existence of a safer alternative design under Texas law.

Ethicon further asserts that the plaintiff has not provided expert testimony that a design defect caused her injuries. Dr. Wheeler's testimony linking the plaintiff's pain to Ethicon's medical device is sufficient to at least create a disputed question of fact on this issue. Thus, Ethicon's Motion on the plaintiff's strict liability design defect claim is **DENIED**.

2. Failure to Warn

Texas, like many jurisdictions, has adopted the learned intermediary doctrine, which applies to strict liability claims. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 169 (Tex. 2012). Under this doctrine, "a manufacturer is required to provide adequate warning to the end users of its product if it knows or should know of any potential harm that may result from the use of its product." *Id.* at 153–154. "In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th

Cir. 1999) (applying Texas law).

Under Texas law, causation—the second element—must be proven by showing “a proper warning would have changed the decision of the treating physician.” *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000)). In other words, the plaintiff must show “that but for the inadequate warning, the treating physician would have not used or prescribed the product.” *Id.* (quoting *Dyer*, 115 F. Supp. 2d at 741). If a physician, as the learned intermediary, does not testify that he or she would not have used or prescribed the product, the causal chain is broken, the plaintiff cannot show causation, and the failure to warn claim fails. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012) (“[W]hen the prescribing physician is aware of the product’s risks and decides to use it anyway, any inadequacy of the product’s warning, as a matter of law, is not the producing cause of the patient’s injuries.”).

Ethicon argues that Ms. Lankston’s implanting physician, Dr. Ely, testified that he was aware of a variety of risks and the plaintiff offered no evidence that additional warnings would have changed Dr. Ely’s mind. The plaintiff counters that while Dr. Ely was aware of general risks associated with mesh products, he was not aware of the severity and frequency of many of the risks associated with the TVT-S. Further, the plaintiff asserts that the issue of whether Dr. Ely would have behaved differently if Ethicon provided all of the necessary information is disputed. The plaintiff provides evidence that after two failures with the TVT-S, Dr. Ely

independently decided to stop implanting the device and that he further testified he would have shared information regarding the dangers of the device with patients.

Evidence that the doctor later decided to use a different product due to his own risk evaluation is not sufficient. The doctor did not testify that he would have changed his mind with adequate warning. Thus, the court **FINDS** that the plaintiff is unable to prove that Ms. Lankston's treating physician would have refrained from prescribing the TVT-S had he received adequate warnings.

The plaintiff's argument that the court should consider what Ms. Lankston would have done had she been adequately warned (i.e., deciding to refrain from having the TVT-S surgery) is unpersuasive. Under Texas law, the learned intermediary doctrine focuses on the adequacy of the warnings to, and the behavior of, the physician, who may make individualized medical judgments "bottomed on a knowledge of both patient and palliative." *Centocor, Inc.*, 372 S.W.3d at 159 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)). What the plaintiff would or would not have done had she received certain warnings is irrelevant to the learned intermediary doctrine. *See Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208 (4th Cir. 2015) (applying Texas law) ("When a plaintiff offers no evidence that a different warning would have changed her physician's decision to prescribe a device, the inadequate warning cannot have caused the plaintiff's injury.").

The plaintiff's strict liability failure to warn claims must fail because the plaintiff is unable to prove that the alleged failure to warn was the producing cause

of Ms. Lankston's injury. Accordingly, Ethicon's Motion on this point is **GRANTED**.

3. Negligent Misrepresentation

Ethicon argues that the plaintiff's negligent misrepresentation claim is essentially a repackaged failure to warn claim that is subject to the learned intermediary doctrine. The learned intermediary doctrine applies with equal force to the plaintiff's negligent failure to warn case. *See Centocor*, 372 S.W.3d 140, 173 (Tex. 2012) (finding the learned intermediary doctrine applies to all claims premised on the manufacturer's alleged failure to warn). Consequently, the plaintiff did not meet her burden of demonstrating that the alleged inadequate warning was the producing cause of the plaintiff's injuries. Accordingly, the court also **GRANTS** Ethicon's Motion with respect to the plaintiff's negligent misrepresentation claim.

B. Negligence and Gross Negligence

"While strict liability focuses on the condition of the product, '[n]egligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production.'" *Am. Tobacco Co.*, 951 S.W.2d at 437 (quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)). "Negligent design and manufacturing claims are predicated on the existence of a safer alternative design for the product." *Id.* Ethicon argues only that summary judgment is proper on these claims because the claims are duplicative of the strict liability claims and because the plaintiff has allegedly failed to offer evidence of a safer alternative design. As discussed above, the plaintiff has proffered sufficient evidence regarding the alleged existence of a safer

alternative design, and the plaintiff's negligence claims are not contingent on the outcome of their strict liability claims; they are independent claims. Ethicon's Motion regarding the plaintiff's negligence claims is **DENIED**.

Under Texas law, gross negligence includes two elements:

- (1) viewed objectively from the actor's standpoint, the act or omission must involve an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and
- (2) the actor must have actual, subjective awareness of the risk involved, but nevertheless proceed in conscious indifference to the rights, safety, or welfare of others.

Mobil Oil Corp. v. Ellender, 968 S.W.2d 917, 921 (Tex. 1998). "Evidence of simple negligence is not enough to prove either the objective or subjective elements of gross negligence." *Id.* The plaintiff offers evidence Ethicon knew before the launch of TVT-S that some women would have severe complications, and that it had a high failure rate, but did not share this information in the IFU. The plaintiff also offers extensive evidence regarding the complications associated with chronic inflammatory responses to the TVT-S. Whether such complications pose the type of "extreme degree of risk" that would implicate liability for gross negligence is best suited for the trier of fact. Ethicon's Motion regarding the plaintiff's gross negligence claims is **DENIED**.

C. Punitive Damages and Discovery Rule and Tolling

Ethicon assert that its Motion challenges all of the plaintiff's claims, which include punitive damages, the discovery rule, and tolling. Mot. Summ. J. 1. Ethicon, however, does not present any arguments regarding these claims. The court will not

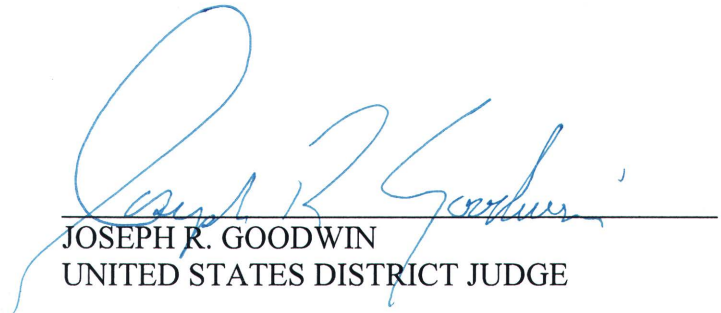
make arguments for Ethicon. Accordingly, Ethicon's Motion regarding the plaintiff's claims for punitive damages, the discovery rule, and tolling is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that Ethicon's Motion for Summary Judgment [ECF No. 93] is **GRANTED in part** and **DENIED in part**. As the plaintiff has conceded these claims, Ethicon's Motion is **GRANTED** with regard to the plaintiff's claims for loss of consortium; negligent infliction of emotional distress; unjust enrichment; manufacturing defect; breach of warranty; fraud; fraudulent concealment; constructive fraud; and Deceptive Trade and Practices Act. Ethicon's Motion regarding the plaintiff's strict liability failure to warn and negligent misrepresentation claims is **GRANTED**. Ethicon's Motion regarding the plaintiff's strict liability design defect, negligence, gross negligence, punitive damages, and discovery rule and tolling is **DENIED**.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 4, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE